DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

July 18, 2001

WARNING LETTER
2001-DT-24

Keith B. Davis, Vice-President
United Fish Distributors, Inc..
1349 Adelaide Street
Detroit, MI 48207

Dear Mr. Davis:

On November 21 thru 29, 2000, the Food and Drug Administration (FDA) conducted an inspection of your facility located at 1349 Adelaide Street, Detroit, MI. The inspection was conducted to determine compliance with the FDA's Seafood HACCP Regulation (21 CFR 123) and the current Good Manufacturing Practice requirements for foods (21 CFR 110).

During the inspection the FDA investigator observed shortcomings in your system that are deviations from the principles of HACCP and the significant requirements of the program. The FDA investigator presented your firm with a form FD-483 which presents the investigator's evaluation of your firm's performance regarding various aspects of the HACCP and GMP requirements. In spite of some of the corrections you have made, we still find your firm is in violation of 21 CFR 123 and 110 causing your products to be deemed adulterated under the provisions of 21 USC 342 (a)(4) because of the following:

1. You must have a HACCP plan that lists the critical limits that must be met, in order to Comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for fresh scombrotoxin species ([redacted] lists a critical limit at the receiving critical control points that is not adequate to control the histamine formation. The critical limit requiring that product must not reach temperature above 40° F does not provide an adequate assurance that the product was maintained at adequate temperatures during transport to your facility. Secondary processors of these products should check for adequacy and presence of cooling media at the time of delivery or obtain documentation of continuous monitoring during transport of each shipment.

2. You must implement the monitoring procedures listed in your HACCP plans for your products, to comply with 21 CFR Part 123.6(b). However, your firm did not follow the monitoring procedures and/or frequencies listed in your HACCP plans for your scombrotoxin forming species, your invertebrate species and your smoked fish products.

   You did not implement the monitoring procedures listed in your plan at the receiving, storage (cooler) and the weigh/pack/labeling critical control points for your scombrotoxin forming species. Specifically, your firm is not monitoring and recording the times and temperatures as listed in your plan.

   Your firm is not following the monitoring procedures listed in your HACCP plan for invertebrate (molluscan shellfish) species at the receiving, storage and packing critical control points. Specifically, your firm is not monitoring and recording the times and temperatures as listed in your plan.

   Your firm is not following the monitoring procedures listed in your HACCP plan at the receiving and storage critical control points for your smoked fish products. Specifically, your firm is not monitoring and recording times and temperatures as listed in your HACCP plan.

3. Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR part 123.7(b). However your corrective action plans for your scombrotoxin (histamine) forming species and your invertebrate (molluscan shellfish) species are not appropriate. Specifically, as stated in your HACCP plans "taking corrective action for all products that have been in temperature greater than 40/45°F for 2 hours" and/or "cooling immediately" are not appropriate. These actions do not ensure that product that has been temperature abused and/or may have already produced toxins is prevented from entering the marketplace.

4. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for seafood salad to control the food safety hazard of pathogens.

   The above-identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

   You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure or injunction.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Also, please include copies of any available documentation demonstrating that corrections have been made.

Your written reply should be directed to Ms. Greta L. Budweg, Compliance Officer, U.S. Food and Drug Administration, 1560 E. Jefferson Ave., Detroit, MI 48207, telephone 313-226-6260 x 107.

Sincerely,

for David M. Kaszubski
Raymond V. Mlecko
District Director
Detroit District